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PTO/SB08A/B (04-03)

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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SHEET 1 of 5

## COMPLETE IF KNOWN

Application Number	10/404512
Confirmation Number	6502
Filing Date	April 1, 2003
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	9188&

## U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	DOCUMENT NUMBER Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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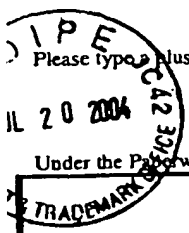
## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	FOREIGN PATENT DOCUMENT Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
SHS		EP 0,508,701B1	10-14-1992	Quest International B.V.		
		EP 0,862,863B1	09-09-1998	Societe Des Products Nestle S.A.		
		EP 1,312,667A1	05-21-03	Wakamoto Pharmaceutical Co., LTD		
		W0 00/41707A1	07-20-2000	Enterprise Ireland		
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		W0 02/083879A2	10-24-2002	Alimentary Health LTD.		
		W0 03/010297A1	02-06-2003	Alimentary Health LTD.		
		W0 03/010298A1	02-06-2003	Alimentary Health LTD.		
		W0 03/010299A1	02-06-2003	Alimentary Health LTD.		
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SHEET 2 of 5

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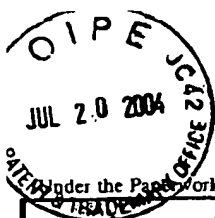
### NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		<del>AGA, Abstracts, Gastroenterology Vol. 118 No. 4</del>	
		<del>HENRY J. BINDER, M.D., "Genes, Bacteria and T Cells: Ingredients for Inflammatory Bowel Disease", Selected Summaries, Gastroenterology 1998; 115: 1605-1609, Vol. 115, No. 6</del>	
		<del>O'MAHONY ET AL., "Probiotic Bacteria and the Human Immune System", Dept. Microbiology and Medicine, National Food Biotechnology Centre, University College Cork &amp; Dept. Surgery, Mercy Hospital, Cork Ireland</del>	
		<del>O'HALLORAN ET AL., "Adhesion of Potential Probiotic Bacteria to Human Epithelial Cell Lines", Departments of Microbiology and Medicine, University College, Mercy Hospital, Cork, Ireland, Dept. of Surgery, Mercy Hospital, Cork, Ireland</del>	
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↓		MARTEAU ET AL., "Potential of Using Lactic Acid Bacteria for Therapy and Immunomodulation in Man", FEMS Microbiology Reviews 12 (1993) 207-220	
↓		FERGUS SHANAHAN, "The Intestinal Immune System", Physiology of the Gastrointestinal Tract, Third Edition, 1994	
		<del>VITTORIO SCARDOVI, "Irregular Nonsporing Gram-Positive Rods", Genus Bifidobacterium Orla-Jensen 1924, 472</del>	
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		<del>MCCRACKEN ET AL., "Probiotics and the Immune System"</del>	
		<del>MCBREARTY ET AL., "Probiotic Bifidobacteria and Their Identification Using Molecular Genetic Techniques", Teagasc, Dairy Products Research Centre, Moorepark, Fermoy, Co. Cork, Ireland</del>	
		Department of Microbiology, University College Cork, Ireland	
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Confirmation Number	6502
Filing Date	April 1, 2003
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
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**NON PATENT LITERATURE DOCUMENTS**

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		<del>O'MAHONY ET AL., "Probiotic Bacteria and Pathogenic Bacteria Elicit Differential Cytokine Responses From Dendritic Cells", XP-001097373</del>	
SHS		CHARTERIS ET AL., "Antibiotic Susceptibility of Potentially Probiotic Bifidobacterium Isolates From the Human Gastrointestinal Tract", Letters in Applied Microbiology 1998, 26, 333-337	
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		BOUHNİK ET AL., "Effects of Bifidobacterium SP Fermented Milk Ingested With or Without Inulin on Colonic Bifidobacteria and Enzymatic activities in Healthy Humans" European Journal of Clinical Nutrition (1996) 50, 269-273	
		CHARTERIS ET AL., "Development and application of an In Vitro Methodology to Determine the Transit Tolerance of Potentially Probiotic Lactobacillus and Bifidobacterium Species in the Upper Human Gastrointestinal Tract" Journal of Applied Microbiology 1998, 84, 759-768 - XP 000929203	
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↓		COLLINS ET AL., "Selection of Probiotic Strains for Human Applications", In. Dairy Journal 8 (1998) 487-490	
		<del>DONNE ET AL., "Probiotics: From Myth to Reality. Demonstration of Functionality in Animal Models of Disease and in Human Clinical Trials" XP-000929176</del>	
SHS		GIBSON ET AL., "Dietary Modulation of the Human Gut Microflora Using Prebiotics", Journal of Nutrition (1998) 80, Suppl. 2 S209-S212	
↓		CHARTERIS ET AL., "Effect of Conjugated Bile Salts on Antibiotic Susceptibility of Bile Salt-Tolerant Lactobacillus and Bifidobacterium Isolates", Journal of Food Protection Vol. 63, No. 10, 2000, pages 1369-1376	
		<del>ARAI ET AL., "Cytokines: Coordinators of Immune and Inflammatory Responses", Annu. Rev. Biochem. 69, 59-782-826</del>	
SHS		GROUX ET AL., "Regulatory T Cells and Inflammatory Bowel Disease", Viewpoint Immunology Today October 1999	
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**INFORMATION DISCLOSURE  
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SHEET 5 of 5

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Application Number	10/404512
Confirmation Number	6502
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First Named Inventor	Chen et al.
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		GBOLUX ET AL., "Regulatory T Cells and Inflammatory Bowel Disease", <u>Viewpoint Immunology Today</u> , October 1999	
SHS		GASCHE ET AL., "IL-10 Secretion and Sensitivity in Normal Human Intestine and Inflammatory Bowel Disease", <u>Journal of Clinical Immunology</u> Vol. 20, No. 5, 2000	
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		POWRIE ET AL., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease in Scid Mice Reconstituted with CD45Rbhi CD4+ T Cells", <u>Immunity</u> Vol. 1, 553-562, October, 1994	
		VAN DAMME ET AL., "The Proportion of Th1 Cells, Which Preval in Gut Mucosa, is Decreased in Inflammatory Bowel Syndrome", <u>Clin Exp Immunol</u> 2001; 125:383-390	
EXAMINER	Shulamith H. Shafer		DATE CONSIDERED 08/07/2006

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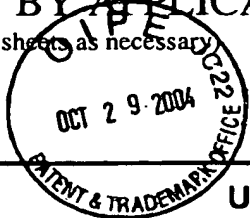
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SHEET 1 of 2



Application Number	10/810,358
Confirmation Number	1244
Filing Date	March 26, 2004
First Named Inventor	Chen et al.
Group Art Unit	1616
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SHS	2	WO 94/04180A2	03/03/1994	Schering Corp.		
SHS	3	WO 94/04180A3	03/03/1994	Schering Corp.		

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SHS	4	HILDESHEIM ET AL., "Simultaneous Measurement Of Several Cytokines Using Small Volumes Of Biospecimens", <u>Cancer Epidemiology, Biomarkers &amp; Prevention</u> , Vol. 11K1, pgs. 1477-1484, November 2002, XP002296946 abstract	
↓	5	ANDUS ET AL., "Imbalance Of The Interleukin 1 System In Colonic Mucosa – Association With Intestinal Inflammation And Interleukin 1 Receptor Agonist Genotype 2", <u>Gut</u> , Vol. 41, 1997, pages 651-657, page 654, column 2-page 655, column 1 figure 2D, XP002296947	
	6	ROGLER ET AL., "Cytokines In Inflammatory Bowel Disease", <u>World Journal of Surgery</u> , Vol. 22, 1998, pages 382-389, XP002296948 the whole document	
	7	O'CALLAGHAN ET AL., "Human Cytokine Production By Mesenteric Lymph Node Cells In Response To Probiotic And Pathogenic Bacteria", <u>Gastroenterology</u> , Vol. 122, No. 4 Suppl. 1, page A-151 DDW Meeting Abstract Nr. S1040, April 2002, XP009036734 the whole document	
	8	MCCARTHY ET AL., "Double Blind, Placebo Controlled Trial Of Two Probiotic Strains In Interleukin 10 Knockout Mice And Mechanistic Link With Cytokine Balance", <u>Gastroenterology</u> , Vol. 122, Nr. 4 Suppl. 1, pages A-389-A390 DDW Meeting Abstract Nr. T962, XP009036733 the whole document	
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9188R& PTO-SB08  
(Revised for P&G use 10/8/2003)

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